IN THE HIGH COURT OF JUDICATURE, ANDHRA PRADESH
AT HYDERABAD

(Special Original Jurisdiction)

MONDAY, THE SEVENTH DAY OF FEBRUARY
TWO THOUSAND AND FIVE

PRESENT

HON'BLE SRI DEVINDER GUPTA, THE CHIEF JUSTICE

and
HON'BLE SRI JUSTICE M.NARAYANA REDDY

WRIT PETITION NO.25888 of 2002

Between:

People for Economical and Effective Medi-care

Regd.No. 1373/94, 3-5-1092/2/C, Venkateswara Colony,
Narayanaguda, Hyderabad, rep. by its Chairman, P.V.R. Bhaskar Rao

..... PETITIONER

AND

1 The Union Government of India Medical, Health & Family Welfare Dept.,

rep. by its Secretary, New Delhi
2 The Government of A.P Medical, Health & Family Welfare Dept., rep. by its

Secretary, Secretariat, Hyderabad
3 The Director of Health
Govt. of A.P., Hyderabad

.....RESPONDENTS

Petition under Article 226 of the Constitution of India praying that in the circumstances stated in the Affidavit filed herein the High Court will be pleased to issue a Writ or order or direction, more particularly one in the nature of Writ of

Mandamus directing the respondents. a) to frame the guidelines based on the International Standards for pre and post Vaccination safety measures and consequently instruct all the medical professionals including the hospitals, non-governmental

organisations to adhere strictly to the guidelines to be framed by the State Government and union Government b) to provide compensatory mechanism to the victims by virtue of adverse affects after any vaccination forthwith.

Counsel for the Petitioner : Sri V.AJAYAKUMAR

Counsel for the Respondent No.1:Sri A.Rajasekhar Reddy, S.C. for Central Govt.

Counsel for Respondents No.2 and 3: G.P. for Medical Health & Family Welfare

The Court made the following :

W.P.No.25888 of 2002

HCJ, & MNR,J

ORAL ORDER: (Per Hon'ble the Chief Justice)

Petitioner has filed this public interest litigation seeking direction against respondents to frame guidelines based on the international standards for pre- and post-vaccination safety measures and consequently instruct all the medical professionals including the hospitals, non-governmental organisations and to adhere strictly to the guidelines to be framed by the State Government and Central Government. Petitioner has also prayed for issuance of direction to respondents to pay compensation to the parents of two months old infant, who died after vaccination of DPT in Basavapoor village, Kohada mandal, Karimnagar district, on 14-11-2002.

Sri I.V.Subba Rao, Principal Secretary to Government, Health, Medical and Family Welfare Department, Government of Andhra Pradesh, Hyderabad, has filed affidavit in reply. It is stated that the immunization activity is organized as per the schedule prescribed by Universal Immunization Programme of Government of India, thoroughly and technically examined at Government of India level. Oral polio vaccine, DPT (Diphtheria, Pertussis, Tetanus vaccine) BCG (Tuberculosis) vaccine, measles vaccine and tetanus toxoid vaccine and Hepatitis-B are given to the beneficiary groups in the programme. The vaccination activity is carried out in all the Government Health care facilities. In rural areas, it is through Primary Health Centres and in Urban areas through Post-Partum units, Urban Health Centres and Area Hospitals. The Doctors involved in the Immunization Programme are qualified and trained people and they routinely undertake pre-vaccination safety as well as post-vaccination measures.

With respect to frequency and nature of vaccine complications, affidavit in reply states that immunization activity involving the vaccines in use in the scheduled

under Universal Immunization Programme of Government of India is considered a very safe and effective means to prevent dangerous and killer diseases of childhood. The benefits of immunization clearly measure the risks. It is not true to say that the after-effects of vaccinations are not effectively addressed by the State and Central Governments. Adequate precautions are taken in the form of keeping life saving drugs like Adrenaline and Cortisone ready for combating possible severe adverse reaction if any at all immunization sessions. The mothers/parents are advised to remain at the site for a period of one hour after vaccination of the child so that any reaction can be immediately noticed and tackled without delay. The mothers/parents are also explained about the possible after effects of vaccination in simple terms that can be understood by them. Further, medicines like Paracetamol are handed over to mothers with instructions to administer to the children in the event of fever or pain/swelling/redness at the vaccination site. The A.P. State Government has constituted Regional teams (comprising specialists from Community medicine, Pediatrics and Microbiology) to investigate the adverse events following immunization and also to supervise the management of such cases. It is also stated that the Hepatitis-B vaccine has been included in the immunization schedule of A.P. State from the year 2002, which is considered a safe vaccine. High quality Hepatitis-B vaccine with certification of W.H.O. pre-qualification has been in use in the State. No single case of serious complication due to Hepatitis-B vaccination in the children has so far been observed in the State.

It is further stated in the affidavit in reply that the Children's Vaccine Programme under PATH (Programme for Appropriate Technology in Health – an international non-governmental organisation) with funds from Bill and Melinda Gates Foundation has entered into partnership project with Government of Andhra Pradesh in the year 2001 to strengthen the immunization programme. Hepatitis-B vaccine has been introduced under this project in the State. Hepatitis-B disease is considered to be a very serious and widely prevalent condition in the country. It has the potential to

cause liver cancer and such similar fatal complications in the middle age. Immunization with the vaccine in the early infancy is regarded as the only effective means to prevent the disease, therefore after careful examination of risks and benefits, this vaccine has been introduced in the immunization schedule. Every year in the State of A.P., 1.5 million infants (children under 1 year of age) are expected to be administered with Hepatitis-B vaccine.

Affidavit further states that the following safety measures are regularly undertaken while conducting the vaccination programme:

a. Parents are counselled about possible mild or severe reactions.

b. The act of voluntarily bringing the child for vaccination is taken as implied consent of the mothers/parents.

c. Detailed records of the beneficiary children are maintained for follow-up of the cases.

d. The vaccine administrators ANMs/Staff are aware of contra-indications for vaccinations. They observe and screen the children to rule out the contra-indications before giving the vaccination.

e. The prescribed storage temperatures for different vaccines are strictly maintained through the use of good quality cold storage equipments like Deep Freezers, Ice Lines Refrigerators, Cold Boxes, and Vaccine Carriers. All the health facilities that render immunization service are equipped with adequate number of cold chain equipment in the State.

f. Emergency life saving drugs like Adrenaline and Cortisone are available with all the institutions."

Thus, it is stated that the guidelines and follow up arrangements are already in place and all safety standards and proper storage of medicines and administration guidelines are maintained and followed under the Immunization Programme. Affidavit also says that the Government once again will examine the issue in the light of recent technical studies and observations of experts. As regards one incident highlighted by the petitioner, it was not due to any negligence or failure to take post-

vaccination steps. In any case, a sum of Rs.5,000/- was paid to the parents of the child, who died after vaccination, towards *ex gratia*.

In view of what has been stated in affidavit in reply, prayer sought by the petitioner had been granted, as there is no reply affidavit filed by the petitioner. Thus, we close the writ petition without any further direction.

Writ Petition stands closed.

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DEVINDER GUPTA, C.J.

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M.NARAYANA REDDY, J

07-02-2005

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..... REGISTRAR

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SECTION OFFICER

To

1 Secretary
The Union Government of India Medical, Health & Family Welfare Dept.,
New Delhi
2 Secretary,
The Government of A.P Medical, Health & Family Welfare Dept..,
Secretariat, Hyderabad
3 The Director of Health
Govt. of A.P., Hyderabad

4) 2 CCs to Govt. Pleader for Medical Health & Family Welfare, High

Court buildings, Hyderabad. (OUT).

5) 2 CD copies

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